REMARKS

Status of the claims

Upon entry of this amendment, claims 49-123 will be pending.

Rejection under 35 U.S.C. § 112, First Paragraph

The Examiner maintained the rejection of claims 82-114 under 35 USC § 112, first paragraph that was set forth in item 7 spanning pages 6-7 of the Office Action mailed July 29, 2003. The Examiner indicates that the rejection was maintained because a copy of the ATCC Deposit Receipt for ATCC Accession Numbers 97810 and 97809 was not present in Applicants' Response filed on October 29, 2003 at the time she examined it. Applicants submit herewith an additional copy of the ATCC Deposit Receipt for ATCC Accession Numbers 97810 and 97809. The Examiner indicated this rejection would be withdrawn upon receipt of a copy of the ATCC Deposit Receipt. Accordingly, Applicants respectfully request that the rejection of claims 82-114 under 35 USC §112, first paragraph be withdrawn.

Rejections under 35 U.S.C. § 112, Second Paragraph

The Examiner maintained the rejection of claims 49-123 under 35 USC §112, second paragraph that was set forth in item 8 spanning pages 7-8 of the previous Office Action mailed July 29, 2003.

In the Office Action mailed July 29, 2003, claims 49, 57, 58, 63, 70, 77, 78, 82, 90, 91, 96, 103, 110, 111, 115, 119 and 120 were held indefinite because it was not clear what the meaning of the phrase "specifically binds" was. In response, Applicants argued, with supporting documentation from textbooks, research manuals, and catalogs, that the phrase "specifically binds" is a term of art which is routinely used, recognized, and understood by those of ordinary skill in the antibody arts and that, therefore, the claims were not indefinite. The Examiner was not persuaded by Applicants' arguments. In maintaining this rejection the Examiner stated that,

> None of the references cited provide a clear definition of what "specifically binds" means, and Applicants statement that "it would be clear to one of ordinary skill in the art that these antibodies preferentially bind to their target antigen to the exclusion of non-related proteins" does not clarify the situation. It is not clear *how* related a protein would have to be to the polypeptide of SEQ ID NO:2 to "specifically bind" an antibody generated against the polypeptide of SEQ ID NO:2, which makes the claims vague and

indefinite. (See Office Action mailed January 28, 2004, page 4, lines 8-14).

Applicants respectfully disagree.

Preliminarily, Applicants note that a definition of antibody "specificity" was provided in Applicants' last response as the Examiner acknowledged at page 3, lines 18-19 of the Office Action mailed January 28, 2004. Moreover, Applicants remind the Examiner that the other references previously submitted (those which did not contain any definition of the term "specifically binds"- Exhibits B and C, namely) were submitted as evidence that the meaning of an antibody that "specifcally binds" to a given polypeptide is so well understood by those of ordinary skill in the art, that a definition of the meaning of "specifically binds" is not required.

To further address the present rejection under 35 U.S.C. § 112, second paragraph, Applicants submit herewith a Declaration under 37 C.F.R. § 1.132 by Dr. Viktor Roschke. As exemplified by Dr. Roschke's curriculum vitae (attached as Exhibit 1 to the Declaration), Dr. Roschke is quite experienced in, and familiar with, the antibody research field. Dr. Roschke's Declaration clearly indicates that on or before January 14, 1997 practitioners who routinely used antibodies in research would have understood the meaning of the term "specifically binds". In particular, Dr. Roschke explains in the Declaration that on or before January 14, 1997 an antibody that "specifically bound" a protein was understood to be an antibody that under empirically optimized antibody binding conditions: a) was useful in biological assays, diagnostic assays, or therapeutic protocols because of its ability to discriminate between the target protein and non-target proteins; b) bound the protein against which it was raised/screened with significantly higher affinity than it bound other proteins (*i.e.*, paralogues and unrelated proteins); and, c) might also bind fragments of the protein and/or variants of the protein against which it was raised/screened (*e.g.*, post-translationally processed forms of the protein, orthologous proteins, and proteins encoded by alternative alleles or alternatively spliced transcripts). *See*, Declaration of Viktor Roschke, page 9, section V(A).

Applicants point out to the Examiner that the Roschke Declaration makes it clear that one of skill the antibody art understands and would have understood the meaning of the term specifically binds. Moreover, the portion of the Roschke Declaration quoted in the preceding paragraph (particularly points b and c) makes it very clear that one of skill in the antibody art

also has and would have had a firm understanding of the scope of proteins that are not 100% identical to SEQ ID NO:2 but that nonetheless may be bound by the claimed antibodies.

Thus, Applicants submit that the Roschke Declaration and the exhibits submitted therewith (*i.e.*, Exhibits 1-6), as well as the arguments and exhibits previously submitted or submitted herein are sufficient to obviate or overcome this aspect of the rejection under 35 U.S.C. § 112, second paragraph, in regard to use of the term "specifically binds." Therefore, Applicants respectfully request that this rejection be reconsidered and withdrawn.

The Examiner also maintained the rejection of claims 50, 51, 71, 72, 83, 84, 104, 105 and 116 under 35 U.S.C. § 112, second paragraph, on the basis that it is not clear what the difference in scope between "binds" as recited in these claims and "specifically binds" as recited in the claims from which these claims depend. Applicants previously argued that 35 U.S.C. § 112, fourth paragraph provides that "[a] claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers" and that the use of the term "binds" in the dependent claim is clear because that "binding" is within the scope of the "specific binding" of the antibody of the claim from which the rejected claims depend. (See pages 20 and 21 of Applicants Response filed October 29, 2003.) The Examiner considered Applicants arguments but did not find them persuasive.

In maintaining this rejection the Examiner stated,

> Applicants appear to be making the case that a subset of the class of antibodies that specifically bind a protein consisting of amino acids 31- 300 of SEQ ID NO:2 will also bind a fragment of the protein that retains an epitope of the larger protein, and that such binding is within the scope of specific binding of the larger protein because the antibody is still recognizing the same protein, albeit a fragment of that protein. (See paragraph spanning pages 4 and 5 of the Office Action mailed January 28, 2004).

Applicants affirm the Examiner's understanding of the claims[1]. Applicants also point out to the Examiner that the Roschke Declaration also refers to antibody "binding" within the context of "specific binding." See, Declaration of Viktor Roschke, page 9, section V(A).

[1] Applicants note for the record that in the first full paragraph on Page 5 of the Office Action Mailed January 28, 2004, the Examiner indicated the claimed antibody will bind the same epitope in a fragment *to the same extent* to which it binds an epitope in the larger protein. Theoretically Applicants agree this is true, but in practice the extent to which an antibody binds an epitope in a fragment of the larger protein against which the antibody was raised, will depend on the extent to which the epitope is present in the fragment in the same conformation in which it is found in the larger protein.

Thus, Applicants submit that 1) the rejected claims are clear, as evidenced by the Examiner's correct articulation of the claims' meaning; 2) that the dependent claims are narrower than the claims from which they depend and therefore do not violate the requirement of 35 U.S.C. § 112, fourth paragraph; and 3) that it is not uncommon for those of skill in the art to describe antibody "binding" within the context of "specific binding" by an antibody. Accordingly Applicants submit that claims 50, 51, 71, 72, 83, 84, 104, 105 and 116 are not indefinite under 35 U.S.C. § 112, second paragraph and respectfully request that this rejection be reconsidered and withdrawn.

CONCLUSION

Applicants respectfully request that the remarks above be entered and made of record in the file history of the instant application. It is believed that these amendments overcome or obviate the outstanding objections and rejections and place the application in condition for allowance. A Notice of Allowance is earnestly solicited. If in the opinion of the Examiner, a telephone conference would expedite prosecution, the undersigned can be reached at the telephone number indicated below.

Finally, if there are any fees due in connection with the filing of this paper in excess of those accounted for on the Fee transmittal submitted herewith, please charge such fees to Deposit Account No. 08-3425.

Respectfully submitted,

Date: March 26, 2004

Michele Shannon

Michele Shannon Reg. No. 47,075
Patent Agent

Human Genome Sciences, Inc.
14200 Shady Grove Road
Rockville, Maryland 20850
(240) 314-4400 x2372 (telephone)

KKH/MS/vsr

American Type Culture Collection

12301 Parklawn Drive • Rockville, MD 20852 USA • Telephone: (301)231-5520 Telex: 908-768 ATCCROVE • FAX: 301-816-4366

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Human Genome Sciences, Inc.
Attn: Robert H. Benson
9410 Key West Avenue
Rockville, MD 20850

Deposited on Behalf of: Human Genome Sciences, Inc.

Identification Reference by Depositor:	**ATCC Designation**
DNA Plasmid 1789595 (PF341)	97809
DNA Plasmid 1789629 (PF341)	97810

The deposits were accompanied by: __ a scientific description _a proposed taxonomic description indicated above.

The deposits were received November 22, 1996 by this International Depository Authority and have been accepted.

AT YOUR REQUEST:

X We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested November 27, 1996. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Rockville, Md. 20852 USA

Signature of person having authority to represent ATCC:

Barbara M. Hailey

Barbara M. Hailey, Administrator, Patent Depository

Date: November 29, 1996